UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	**Oral Argument Requested**

MANUFACTURER AND PHARMACY DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION TO EXCLUDE THE OPINIONS OF DR. RENA CONTI

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PRELIMINARY STATEMENT

Defendants' opening brief identified numerous flaws in Dr. Rena Conti's classwide damages model that render her opinions unreliable and therefore inadmissible. Plaintiffs' effort to defend her opinions fails for several reasons.

First, Plaintiffs assert that Defendants are merely challenging Dr. Conti's ultimate conclusion that the Valsartan-containing drugs ("VCDs") at issue in this litigation had zero value. This assertion mischaracterizes Defendants' motion. Defendants' challenges focus on the unreliability of the analysis underlying Dr. Conti's worthlessness opinion, in particular her failure to incorporate the therapeutic benefits of VCDs into her model—they do not simply attack her conclusions.

Second, with respect to Dr. Conti's point-of-sale opinions, Plaintiffs argue that her failure to incorporate post-sale adjustments such as rebates, government subsidy payments and refunds into her model can be cured by an unspecified, future amendment to her model because Plaintiffs are not required to provide exact individual damages at this stage. But the question at issue is whether Dr. Conti's model as described to date is reliable and fits the facts of the case. Because her model fails to incorporate post-sale adjustments, it cannot satisfy these requirements.

Finally, Plaintiffs attempt to justify Dr. Conti's failure to address pharmacy costs in her unjust enrichment model on a variety of grounds, arguing, among other things, that the model does in fact address costs, that deficient discovery is to blame,

and that it is Defendants' burden to address those costs. In so arguing, however, Plaintiffs ignore the fundamental reason why pharmacy costs were excluded and why Dr. Conti's opinion is unreliable: Dr. Conti improperly assumed that pharmacy profits can be measured solely by consumer payments. They cannot.

For these reasons, discussed further below, Plaintiffs' arguments should be rejected, and Dr. Conti's opinions should be excluded.

ARGUMENT

I. DR. CONTI'S WORTHLESSNESS OPINION IS UNRELIABLE.

In their opening brief, Defendants explained that Dr. Conti's entire model is unreliable because it is premised on the erroneous assumption that the VCDs are worthless. Plaintiffs' attempts to justify Dr. Conti's worthlessness opinion all fail.

First, Plaintiffs' argument that Defendants' criticisms are directed to Dr. Conti's conclusions rather than her methodology, Opp'n at 2, 22-23, mischaracterizes Defendants' motion. As Defendants explained in their opening brief, Dr. Conti's methodology is unreliable because: (1) she conflates price and value; (2) she ignores real-world evidence that FDA-approved VCDs provided substantial benefits to consumers and TPPs;[1] and (3) "legitimate supply" is not a

[1] Plaintiffs attempt to support Dr. Conti's opinion by arguing that Defendants' experts conceded that therapeutic value is irrelevant to economic damages under a benefit-of-the-bargain theory. Opp'n at 25. In fact, Plaintiffs' counsel asked Defendants' experts what an appropriate measure of damages would be if the VCDs at issue were assumed to be worthless. *See* ECF 2057, Ex. 249 at 144:16-23.

meaningful economic concept for determining value. Mem. at 9. These arguments plainly challenge the ***manner*** in which Dr. Conti reached her ultimate opinion, not the conclusion itself. Courts in this Circuit have regularly excluded such flawed opinions under *Daubert*. *See, e.g.*, *Ctr. City Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 204 (E.D. Pa. 2017).

Second, Plaintiffs attempt to distinguish Defendants' authority on the ground that Defendants' cases did not involve prescription medications, noting that *Shahinian v. Kimberly Clark*, No. 14-8390, 2017 WL 11595343 (C.D. Cal. Mar. 7, 2017), involved medical gowns, and *Center City Periodontists* involved a dental product that was "likely distinguishable." Opp'n at 31 n.13. But Plaintiffs offer no reason why those factual differences undermine the fundamental holdings of the cases Defendants cited: i.e., that an expert cannot simply posit that a product is worthless without a reliable basis for that conclusion.

Plaintiffs argue that two other cases cited by Defendants, which ***did*** involve prescription medications, are nonetheless distinguishable because they involved "overlapping claims for personal injury and product liability type claims." Opp'n at 31. But both cases involved similar legal theories to those at issue here. *See In re Baycol Prods. Litig.*, 218 F.R.D. 197, 213 (D. Minn. 2003) (addressing worthlessness theory in connection with "refund class" separate from personal injury class); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 62 (S.D.N.Y. 2002)

(addressing class of users "who have not manifested physical injury").

Plaintiffs' own cases, by contrast, are inapposite or wrongly decided. Plaintiffs cite *Krueger v. Wyeth, Inc.*, No. 03CV2496, 2011 WL 8971449 (S.D. Cal. Mar. 30, 2011), for the proposition that full refund models are an appropriate measure of damages in cases involving allegedly misbranded drugs. Opp'n at 14-16, 31. But the cited opinion did not involve a *Daubert* challenge, and in any event, the *Krueger* court later granted summary judgment to the defendant on the plaintiffs' claims under the California Consumer Legal Remedies Act, after finding that plaintiffs had not established a "price less value received" model; this ruling makes it clear that the court believed "value received" was relevant for at least some of the plaintiffs' claims. *Krueger v. Wyeth, Inc.*, 396 F. Supp. 3d 931, 948-49 (S.D. Cal. 2019). And although the court in *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, No. 13-4663, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019), admitted Dr. Conti's testimony in a third-party payor ("TPP") case, that court misapplied *Daubert* law in finding that the deficiencies in Dr. Conti's model went to credibility rather than admissibility, *id.*, because the Court is required, as the gatekeeper, to determine whether an economic model is reliable. *See Citizens Fin. Grp., Inc. v. Citizens Nat'l Bank of Evans City*, 383 F.3d 110, 121 (3d Cir. 2004) (rejecting weight argument where the underlying "methodology was fundamentally flawed"); *Lithuanian Commerce Corp. v. Sara Lee Hosiery*, 179 F.R.D. 450, 459 (D.N.J. 1998)

("[D]istrict courts must evaluate proffered expert evidence in the first instance rather than leaving the task for the jury to sort through.").

Plaintiffs' other cases only confirm that an appropriate refund damages model should account for the therapeutic benefit provided by the product. *See, e.g.*, *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015) (finding that a full-refund damages model could be appropriate under the plaintiffs' theory of liability in a probiotics case because "[i]f, as alleged, the bacteria does nothing, then the capsule is worthless") (citation omitted).[2] Nobody has ever contended that the VCDs did "nothing"; to the contrary, the record is undisputed that they provided therapeutic benefits to patients with high blood pressure. Because Dr. Conti's model fails to account for those benefits, her opinions are not reliable, do not fit Plaintiffs' theory of liability and should be excluded.

II. DR. CONTI'S POINT-OF-SALE OPINION IS UNRELIABLE.

Defendants also explained in their opening brief that Dr. Conti's damages model is unreliable because she myopically focuses on point-of-sale payments, while ignoring other real-world factors that affect the true cost of VCDs for consumers and TPPs. Mem. at 16-18. Plaintiffs respond with a litany of meritless

[2] *See also Rikos*, 799 F.3d at 527 (Cohn, J., concurring) (concurring opinion recommending that the district court bifurcate the issue of whether the product provided any therapeutic benefit to any class member; "if . . . Plaintiffs' proofs fail to establish that Align has no digestive health benefits, the case should be dismissed").

arguments.

First, Plaintiffs ignore the authority cited by Defendants holding that damages models that exclude factors relevant to Plaintiffs' alleged injuries are unreliable and thus inadmissible. *See* Mem. at 16. In particular, although Plaintiffs tout Dr. Conti's knowledge of the "complex pharmaceutical industry supply chain dynamics" that ostensibly relate to their damages theory, Opp'n at 30, they fail to address Defendants' authority holding that damages models involving prescription medications that focus only on point-of-sale transactions are unreliable and inadmissible "given the realities of the pharmaceutical industry." *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 146 (E.D. Pa. 2015) (cited in Mem. at 16).

Instead, Plaintiffs propose to retroactively cure the flaws in Dr. Conti's damages model, arguing that Dr. Conti could amend her model in some unspecified way to account for any post-sale refunds or credits if directed to do so by the Court or jury. Opp'n at 27-28. Federal courts routinely reject such arguments; an expert must show her work before an opinion is admitted, not after. *See, e.g.*, *Ang v. Bimbo Bakeries USA, Inc.*, No. 13-cv-01196, 2018 WL 4181896, at *14-15 (N.D. Cal. Aug. 31, 2018) (rejecting damages expert's "attempts to postpone his explanation of how he will account for" "other factors . . . that may affect the value derived from the products—and which may be based on something other than [d]efendant's alleged

misbranding" until after class certification).[3]

Second, Plaintiffs argue that the need to provide individualized damages calculations due to potential offsets, rebates, or other items would not preclude class certification or render an expert's calculations unreliable. Opp'n at 28. But none of Plaintiffs' authorities addressed whether the damages models at issue were reliable or admissible. Instead, those courts either were not faced with a damages model or declined to address the reliability of the plaintiffs' damages models finding them unnecessary in ***securities*** cases.[4] Notably, while the Third Circuit in *Neale v. Volvo*

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[3] *See also Lancaster v. Harrow*, No. 17-cv-634, 2018 WL 3650119, at *5 (M.D. Fla. Mar. 28, 2018) (striking expert who merely "provide[d] a description of the methodology he ***would*** use"), *report & recommendation adopted*, 2018 WL 3650043 (M.D. Fla. Apr. 12, 2018); *In re Emerson Elec. Co. Wet/Dry Vac Mktg. & Sales Litig.*, MDL No. 2382, 2022 WL 670131, at *3 (E.D. Mo. Mar. 7, 2022) (denying class certification after excluding damages expert who merely "advised that he ***would*** incorporate [relevant] considerations in his final computation"); *see also In re Emerson Elec. Co. Wet/Dry Vac Mktg. & Sales Litig.*, MDL No. 2382, 2021 WL 5003102, at *2 (E.D. Mo. Oct. 28, 2021) (excluding expert whose supplemental report stated only that his prior methodology could "be easily transferred, replicated, applied and/or amended, as applicable" without demonstrating that this was so).

[4] *See In re Novo Nordisk Sec. Litig.*, No. 17-cv-00209, 2020 WL 502176, at *9 (D.N.J. Jan. 31, 2020) (holding that the court "need not assess the validity of [p]laintiffs' damages model at this stage" because "common issues predominate all other issues of law and fact" in a securities action) (citation omitted); *W. Palm Beach Police Pension Fund v. DFC Glob. Corp.*, No. 13-6731, 2016 WL 4138613, at *11 (E.D. Pa. Aug. 4, 2016) (questioning the applicability of *Comcast* to securities cases); *City of Sterling Heights Gen. Emps.' Ret. Sys. v. Prudential Fin., Inc.*, No. 12-5275, 2015 WL 5097883, at *7 (D.N.J. Aug. 31, 2015) (the court "need not consider the reliability of Professor Feinstein's damages model at this stage" in a securities action).

Cars of North America, LLC, 794 F.3d 353, 375 (3d Cir. 2015) (cited in Opp'n at 28), vacated a district court's denial of class certification that had been based on the plaintiffs' failure to provide a damages model with their initial motion, on remand, the district court again denied the plaintiffs' renewed motion for class certification because plaintiffs' damages model failed to provide a reliable approximation of the class's damages. *Neale v. Volvo Cars of N. Am., LLC*, No. 10-4407, 2021 WL 3013009, at *14 (D.N.J. July 15, 2021) (noting that the court "may not 'uncritically accept' such opinion testimony without first conducting a 'rigorous analysis' as to its persuasiveness") (citation omitted).

Third, Plaintiffs suggest that Dr. Conti need not account for offsets at this time because damages need not be reduced to a mathematical certainty at the class certification stage. Opp'n at 29. But Plaintiffs' authorities do not support the proposition that a damages expert's burden to establish reliable methods is more lax at the class certification stage. To the contrary, they declare that, even if mathematical precision may await later stages of the case, the expert must be able to identify a reliable method to account for all factors relevant to the ultimate damages calculation. For example, in *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, 421 F. Supp. 3d 12 (E.D. Pa. 2019), *aff'd*, 967 F.3d 264 (3d Cir. 2020) (cited in Opp'n at 29), the court concluded that the expert's failure to account for the impact of "generic bypass" in his antitrust damages calculations did

not make his opinion unreliable because the expert's rebuttal report explained *how* he would adjust his model to account for that concept. *Id.* at 44.[5] Here, Dr. Conti has repeatedly refused to incorporate post-sale adjustments into her damages model and has offered no explanation for how she would do so at some point in the future.

Finally, Plaintiffs argue that similar models have been accepted by other courts, Opp'n at 29-31, but this argument ignores the substance of Defendants' point-of-sale argument, which is that, even if the Court were to accept Plaintiffs' argument that VCDs are worthless and that Plaintiffs are therefore entitled to a "full refund," such a refund must reflect the actual cost incurred by Plaintiffs, and not simply the amount paid at the time the product was dispensed.[6] Plaintiffs' cases offer no guidance on this issue because they generally involve over-the-counter products purchased directly by the consumer, rather than the prescription medication market,

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[5] *Page v. State Farm Life Insurance Co.*, No. SA-20-CV-00617-FB, 2022 WL 406415 (W.D. Tex. Feb. 10, 2022), Plaintiffs' other case on this point, is even farther afield. Plaintiffs cite *Page* for the proposition that "post-verdict class damages can be adjusted if the jury finds any offset appropriate," Opp'n at 29, but that part of the ruling pertained to the defendant's argument that class certification was improper because the defendant had identified 29 class members (out of 24,000) as to which it was entitled to an offset. *See* 2022 WL 406415 at *13. The *Page* ruling had nothing to do with the admissibility of expert opinions that fail to account for far more sweeping and variable offsets.

[6] For TPPs that offer Medicare Advantage plans, Dr. Conti's point-of-sale model fails to account for the reimbursements that TPPs received from the federal government for Defendants' VCDs.

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which is characterized by complicated pricing and rebates.[7]

For all of these reasons, Plaintiffs' arguments fail, and Dr. Conti's point-of-sale opinions should be excluded.

III. DR. CONTI'S PHARMACY-RELATED UNJUST ENRICHMENT OPINIONS ARE UNRELIABLE.

The Pharmacy Defendants made one defendant-specific argument regarding Dr. Conti's damages opinions: that her formula for pharmacy unjust enrichment damages (and therefore also her calculation for the same) is unreliable and lacking any methodology. This is so because Dr. Conti's "methodology" for calculating what she labels as Pharmacy "profits" was simply to use the "total cost paid" by the consumer for VCDs as reported in the data produced by the Pharmacy Defendants. At her deposition, Dr. Conti affirmed her opinion—untethered to any academic literature—that pharmacy profits (i.e., unjust enrichment damages) must be calculated without regard to what pharmacies paid for a drug or even all of the reimbursements that pharmacies received for a drug from third-party payors. *See, e.g.*, Conti Dep. II 171:21-172:3, 173:2-17, 175:21-177:19 (Mem. Ex. 3 (ECF 2040-

[7] *Steroid Hormone Prod. Case*, 181 Cal. App. 4th 145, 150 (2010), *as modified on denial of reh'g* (Feb. 8, 2010) (over-the-counter steroid); *In re Amla Litig.*, 282 F. Supp. 3d 751, 767-68 (S.D.N.Y. 2017) (beauty product); *Rikos*, 799 F.3d at 502 (over-the-counter nutritional supplement); *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, 509 F. Supp. 3d 116, 192 (D.N.J. 2020) (over-the-counter product; addressing admissibility of expert testimony on causation, not damages).

5).

Plaintiffs' response is confused. On the one hand, Plaintiffs agree that Dr. Conti's formula for calculating liability damages ***is the exact same*** as her formula for calculating pharmacy unjust enrichment damages. *See* Opp'n at 13 ("With the exception of Wholesaler Defendants' Unjust Enrichment damages . . . Dr. Conti calculates these aggregate damages as the total cost paid, by either the consumer or TPP class member."). On the other hand, Plaintiffs seemingly argue that Dr. Conti's formula ***in fact*** considers costs. *See id*. at 33 ("Dr. Conti reliably opines that Downstream Defendants' ill-gotten gains from the at-issue VCDs they sold is presentable as revenue minus costs.").

The truth is that Dr. Conti did not consider "revenue minus costs," either as a practical matter ***or*** from a theoretical perspective. Dr. Conti believes that pharmacy "profits" can be determined without considering all the revenue that pharmacies received (revenue from TPPs does not factor into her formula) and without considering any type of costs outside of dispensing costs, such as the cost of the vial and paper bag. *Cf.* Opp'n 36 at n.16 (arguing that cost data and TPP sales data are tethered for profits).

Plaintiffs offer only one argument in defense of Dr. Conti's failure to proffer any reliable methodology to determine pharmacy profits: they blame discovery.[8] This argument fails. Dr. Conti ***could have*** opined that pharmacy profits are equal to revenues (from both TPPs and consumers) minus costs (including the cost of the drug), but that she could not yet calculate those profits because the Pharmacy Defendants had not produced the relevant data. Indeed, she offered a version of that opinion for Wholesalers' profits. For Pharmacies, however, she created a formula out of whole cloth without ever attempting to consider costs as even a theoretical variable. For the reasons explained in Defendants' opening brief, there is no sound economic rationale for excluding cost as a variable in calculating profit. Mem. at 23-26. Tellingly, ***Plaintiffs themselves*** do not attempt to justify this formula, instead suggesting they can provide it later. *See* Opp'n at 40. But a party cannot defend an

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[8] The Pharmacy Defendants dispute Plaintiffs' recitation of the discovery history and further emphasize that Judge Schneider denied Plaintiffs' request for TPP and cost information without prejudice (ECF 507), and that Plaintiffs had the opportunity to ask at least general questions—even if not tethered to specific data or dollar values—regarding sourcing and purchasing during the 30(b)(6) depositions of the Pharmacies. Regardless, Plaintiffs' arguments regarding discovery—including any possible objections the Pharmacy Defendants have to future discovery requests—are a distraction from the real issue. Dr. Conti herself believes that non-dispensing costs—including, most strikingly, the cost to purchase the drug in the first place—are wholly irrelevant to her formula for determining pharmacy profits. In other words, even if Plaintiffs had sought, and Pharmacies had produced, cost data in discovery, Dr. Conti's own testimony establishes that she would have ignored those data because she considers them irrelevant to her measure of profits. *E.g.*, Conti Dep. II 93:18-96:5, 172:22-173:8).

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expert's opinions by contradicting her, *see Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672-73 (6th Cir. 2010) (rejecting counsel's effort to redefine the expert's opinion through briefing because the expert's "opinion cannot escape its own logic"), and Dr. Conti herself unreliably insists that she does not need the cost data to calculate pharmacy profits, Conti Dep. II 172:22-173:8.[9]

Plaintiffs' cited caselaw does not help them. First, Plaintiffs cite cases to argue that it is Defendants' burden to demonstrate costs. Opp'n at 37. Although the Pharmacies challenge that premise, it is irrelevant here, because Dr. Conti is affirmatively stating through her theoretical formula that the costs Defendants could potentially seek to exclude from profits (for example, the cost of the drug) should ***not*** factor into the analysis of pharmacy profits. *See* Conti Dep. II 89:20-90:6 (agreeing from an academic perspective that she only wants to include "dispensing costs" in her unjust enrichment formula, which is different from "retailer costs").

Next, Plaintiffs cite an antitrust case to argue that cost disputes are fodder for cross-examination. *See* Opp'n at 38. But in that case, the expert "persuasively explained and analyzed" why a ***particular*** cost should not be considered. *In re Blood*

[9] Besides contradicting Dr. Conti's own statement, Plaintiffs' hollow assurance that these costs can be incorporated is insufficient. Federal courts routinely exclude expert testimony that simply promises to do the work later. *See supra* at 7 n.3 (citing *Lancaster*, 2018 WL 3650119, at *5; *In re Emerson Elec.*, 2022 WL 670131, at *3; *In re Emerson Elec.*, 2021 WL 5003102, at *2).

Reagents Antitrust Litig., MDL No. 09-2081, 2015 WL 6123211, at *17 (E.D. Pa. Oct. 19, 2015). By contrast, here, Dr. Conti never attempts to articulate ***why*** pharmacy profits are supposedly measured only at the point of sale, without regard to revenues and costs. Indeed, Dr. Conti could not cite to a single piece of literature to support her opinion on pharmacy profits. Conti Dep. II 177:9-179:7.

Finally, Plaintiffs cite *In re Actiq Sales & Marketing Practices Litigation*, No. 07-4492, 2014 WL 3572932 (E.D. Pa. July 21, 2014), but that case, at most, highlights what Dr. Conti failed to do here. In *Actiq*, the plaintiff's expert calculated gross product sales, deducted product-specific costs (including cost of goods sold, rebates and marketing expenditures), and then applied additional steps to relate the subsequent calculations solely to the at-issue conduct. *Id.* at *5. The defense first challenged the expert's calculation of gross product sales because the expert relied on a report produced in discovery by the defendant to arrive at gross product sales. *Id.* at *6. The court determined that the expert had taken "appropriate strides" to limit her use of the report, had submitted questions to defendant in order to verify line items in it, and taken steps to inform her understanding of its contents. *Id.* Notably, the defense's rebuttal expert did not challenge that the calculation was fairly conservative. Next, the defense challenged the expert's failure to use cost accounting principles in considering certain fixed and indirect costs. *Id.* at *8-9. The *Actiq* court found that disputes over these marginal costs "represent a difference of

opinion" and that the plaintiff's expert had "outline[d] her reasons" for her calculations. *Id.* Dr. Conti, by contrast, testified repeatedly that she did not ***need*** cost information, without ever explaining ***why*** those costs were irrelevant. Unlike the expert in *Actiq*, Dr. Conti took the unreliable, and thus inadmissible, position that direct procurement costs are "of no moment" to her profit calculation.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Conti's opinions purporting to calculate damages attributable to the Manufacturer and Pharmacy Defendants in their entirety.

Dated: June 16, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 16, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

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